SECTION 6
510(k) SUMMARY

510(k) Notification K111241

AUG 29 2011

GENERAL INFORMATION

Applicant:

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U.S.A.
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Contact Person:

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Date Prepared: August 12, 2011

Classification:

21 CFR§878.4683, Class II

Product Code:

OKO

Trade Name:

SNaP® Wound Care System

Generic/Common Name:

Non-powered suction apparatus device intended for negative pressure wound therapy

Predicate Device:

SNaP® Wound Care System (K111393)

SECTION 6
510(k) SUMMARY

Intended Use:

The SNaP Wound Care System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing through the removal of excess exudates, infectious material and tissue debris. The SNaP Wound Care System is indicated for removal of small amounts of exudate from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), surgically closed incisions, flaps and grafts.

Product Description:

The SNaP Wound Care System is a non-powered, portable, single-use suction device intended for wound management via application of negative pressure to the wound for removal of fluids, including wound exudate, irrigation fluids, and infectious materials. The SNaP Wound Care System is designed to provide active wound treatment through the removal of excess exudates, infectious material and tissue debris. The SNaP Wound Care System is indicated for removal of small amounts of exudate from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), surgically closed incisions, flaps and grafts. The SNaP Wound Care System utilizes dedicated constant-force springs to mechanically generate the negative pressure gradient.

The SNaP Wound Care System is used in conjunction with the SNaP Dressing Kit.

Substantial Equivalence:

This Special 510(k) premarket notification is for the SNaP Wound Care System, which is a modified version of the cleared SNaP Wound Care System (K111393). The minor design modification implemented to develop the modified SNaP System includes a change to the SNaP Dressing Kit to incorporate the use of a hydrophobic polyurethane foam. There have been no changes to the other components of the SNaP System as a result of this design change. The design modifications outlined in this Special 510(k) premarket notification do not (1) affect the intended use or (2) alter the fundamental scientific technology of the device. The modified SNaP System shares the same intended use, the same technological characteristics and the same principles of operation as the predicate device. The modified SNaP System and the cleared SNaP System (K111393) are both non-powered, portable, single-use suction devices intended for wound management via application of negative pressure to the wound for removal of fluids, including wound exudate, irrigation fluids and infectious materials. Both systems utilize dedicated constant-force springs to mechanically generate the negative pressure gradient. Any differences between the devices do not raise any new issues of safety or effectiveness.

SECTION 6
510(k) SUMMARY

Testing in Support of Substantial Equivalence Determination:

The SNaP Wound Care System and its components were evaluated to ensure conformance to design specifications. The testing performed includes:

- Bench testing conducted on the modified SNaP Wound Care System to assess the ability to deliver negative pressure wound therapy comparable to the predicate device (K111393)
- Biocompatibility testing

Summary:

The SNaP Wound Care System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Spiracur, Inc.
% Experien Group, LLC
Ms. Sarah Canio
755 N. Mathilda Avenue
Sunnyvale, California 94085

AUG 29 2011

Re: K112341
Trade/Device Name: SNaP® Wound Care System
Regulation Number: 21 CFR 878.4683
Regulation Name: Non-Powered suction apparatus device intended for negative pressure wound therapy
Regulatory Class: II
Product Code: OKO
Dated: August 12, 2011
Received: August 15, 2011

Dear Ms. Canio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 5
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K112341

Device Name: SNaP® Wound Care System

Indications For Use:

The SNaP® Wound Care System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing through the removal of excess exudates, infectious material and tissue debris. The SNaP Wound Care System is indicated for removal of small amounts of exudate from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), surgically closed incisions, flaps and grafts.

Prescription Use _X_ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112341